

## **REMARKS**

The Examiner's comments from the Office Action mailed September 27, 2007 have been carefully considered. Claims 17, 19 and 39-62 are pending. Claims 41, 47, 59 and 62 have been amended. Support for the amendments can be found in at least Figures 1-3 and the related description of those Figures in the present application. No new matter has been added. Reexamination and allowance of the pending claims is respectfully requested.

Claims 17, 19, and 39-62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi (US 6,325,826) in view of Vrba (US 6,168,621). Applicants respectfully traverse this rejection.

The pending claims are directed to a system that includes a balloon catheter and a stent. The catheter includes a balloon that is positioned within a body of the stent and expands the stent body when inflated. The stent includes plurality of movable members that are movable into a radially outward orientation upon expansion of the stent by the balloon.

In contrast, Vardi discloses with reference to, for example, Figures 7-9, a main stent 40 with an expandable portions 38 surrounding an opening 16, wherein the expandable portions are moved into a radially outward orientation by passing a balloon 25 along a branch guidewire 36 through the opening 16 and then inflating the balloon 25. The expandable portions 38 are not movable into the radial outward orientation when the main body portion of the stent 40 alone is inflated. It is only by passing a balloon catheter through the opening 16 and expanding that balloon catheter that the expandable portions 38 are moved into the radial outward orientation.

Vrba discloses a balloon expandable stent 14 that includes self-expanding parts 12 at a proximal end thereof. The parts 12 are held in a restricted state (unexpanded) by a retractable sheath 20. In use, the stent 14 (enclosed within the sheath 20) is first positioned extending into a branch vessel 24 with the parts 12 remaining within a main vessel 26. The sheath 20 is then retracted proximally thereby permitting the parts 12 to flare outward within the main vessel 26. The flared parts 12 act as an anchor to keep the stent 14 from advancing distally in the branch vessel 24. Thereafter, the balloon expandable portion of the stent 14 is expanded into engagement with the branch vessel 24 by inflation of a balloon 16 of the catheter 18.

Vrba fails to disclose moving the parts 12 into a radially outward orientation by expansion of the balloon expandable portion of the stent 14. Vrba actually teaches away from such a construction and operation. The balloon expandable portion of the stent 14 disclosed by

Vrba could not expand without first retracting the sheath 20, which retraction automatically permits movement of the parts 12 into the radial outward orientation. Vrba fails to disclose moving the parts 12 into the radial outward orientation after or even concurrently with expansion of the balloon expandable portions of the stent 14. Further, providing the parts 12 in the radial outward orientation is taught by Vrba to be an important step in anchoring the stent 14 in a correct longitudinal direction prior to expanding the balloon expandable portion of the stent 14 via inflation of the balloon 16.

Therefore, modifying the stent taught by Vardi with the expandable parts 12 taught by Vrba fails to disclose or suggest the limitations "in the unexpanded condition the plurality of movable members being retained substantially within the circumferential plane of the stent wall and in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall to form a scaffold," as required by claim 17 and 62; "the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement," as required by claim 47; "the movable members configured as self expandable structures that move from an unexpanded position retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall when activated by expansion of the stent wall," as required by claim 57; and "the movable members being expandable by expansion of the single balloon," as required by claim 61. Applicants submit that the limitations of claims 17, 47, 57, 61 and 62 and the claims that depend from them, would not be obvious to one of ordinary skill in the art reviewing the disclosures of Vardi and Vrba, alone or in combination. Applicants do not otherwise concede the correctness of the rejection and reserve the right to make additional arguments if necessary.

Claims 41-56, 59, 60 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi (US 6,325,826) in view of Myler (US 5,632,762). Applicants respectfully traverse this rejection.

As discussed above, Vardi discloses movement of expandable members 38 by passing a balloon catheter 25 through an opening 16 in a sidewall of the stent 40, and then inflating the balloon. Vardi does not disclose or suggest in any way movement of the expandable members

38 by inflation of a balloon catheter positioned within the main body of the stent 40 (i.e., balloon catheter not extending through the opening 16).

Myler discloses with reference to Figures 2 and 7 a balloon 24 used to expand a stent 44. The balloon 24 includes segments A-C, wherein the third, proximal positioned segment C had a diameter significantly greater than the diameters of segments A,B. The enlarged diameter of segment C extends around an entire circumference of the balloon 24 and is symmetrical about a longitudinal axis of the balloon 24. The balloon 24 is used to flare a proximal section 48 of the stent 44 to engage the proximal section 48 within a main vessel 30 while the distal sections of the stent 44 are engaged within a branch vessel 28. The increased diameter of the segment C thus has a construction to accomplish the specific purpose of flaring a proximal section 48 of a stent 44 to anchor that portion of the stent 44 within the main vessel.

In contrast, the claimed invention relates to moving portions of a stent, wherein the stent is positioned within a main vessel, into a branch vessel using a balloon that is also positioned in the main vessel. One of skill in the art would not look to Myler for a teaching of the limitations of claims 41-56, 59, 60 and 62, since Myler is focused on an increased diameter portion of a balloon that anchors a portion of a stent in a main vessel while the main body of the stent is already positioned in a branch vessel.

Furthermore, the combination of Vardi with Myler fails to meet the limitations of claims 41-56, 59, 60 and 62. Replacing the balloon 25 disclosed by Vardi with the balloon 24 disclosed by Myler still results in a balloon passing along a guidewire and through an opening 16 in stent sidewall and subsequent inflation of the balloon to move expandable portions 38 into a radial outward orientation. The increased diameter portion C of the balloon 24 would remain positioned within the main vessel 8 of Vardi, which is internal the main body of stent 40, and would not influence movement of the expandable portions 38. Thus, the combination of Vardi and Myler does not disclose or suggest a balloon positioned within the main body of the stent, wherein the balloon includes a bulge portion, and the bulge portion is used to move the expandable portions of the stent into a radial outward orientation.

Still further, Vardi and Myler fail to disclose or suggest a "single balloon comprises an elongate body region and a bulge region protruding radially outward from the body region when expanded, the bulge region being positioned at a location between a proximal end and a distal end of the body region, and positioned at a predetermined circumferential location spaced around

a circumference of the body region," as required by claims 41 and 47, or "wherein the single balloon comprises an elongate body region and a bulge region protruding radially outward from the body region when expanded, the bulge region extending around less than an entire circumference of the body region," as required by claims 59 and 62. The increased diameter section C of the balloon 24 disclosed by Myler extends around an entire circumference of the balloon. Therefore, Vardi and Myler fail to disclose or suggest every limitation of claims 41-56, 59, 60 and 62 for this additional reason.

### **Conclusion**

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance. If a phone conference would be helpful in resolving any further issues related to this matter, please contact Applicants' attorney listed below at 612-371-5387.

Respectfully submitted,



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